

## **REMARKS**

Applicants note that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the amended Claims (or similar Claims) in the future.

In the Office Action dated 8/24/05, the Examiner issued two rejections under 35 U.S.C. 112, first paragraph. Each of the rejections is discussed in greater detail below.

### **I. The Claims are supported by Written Description**

The Examiner has rejected Claims 4-10 under 35 U.S.C. 112, first paragraph as allegedly lacking written description (Office Action, pg. 2). In particular, the Examiner states "Although the specification states 21 siRNA sequence were synthesized and are targeted to a rat Kv3.4 gene (see page 67, line 4), the specification does not provide the sequences of the 21 siRNA and further does not provide information regarding what particular structure is directed against any mRNA encoding a Kv3.4 protein wherein the siRNA is capable of inhibiting Kv3.4 expression in any neuronal cell." (Office Action, pg. 3). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 4 to include the element of an siRNA directed towards a specific Kv3.4 target defined by positions 2222-2283 of GenBank Accession number X62841. The Applicants provide written description for the target sequence on page 66, lines 4-13. The Applicants have further provided exemplary siRNA sequences on page 67, lines 4-12. The Applicants provide experimental data and an experimental protocol for siRNAs targeting the target sequence of Claim 4 (See e.g., pages 66-67). In addition, the Applicants describe methods for targeting Kv3.4 target sequences in a variety of cell types (See e.g., Specification, pgs. 36-44). As such, the Applicants submit that they have provided adequate written description for the presently claimed invention and respectfully request that the rejection be withdrawn.

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

The Applicants have added new Claim 17, which is directed towards specific siRNA target sequences. Support for this claim can be found on page 67, lines 4-12 and on page 66, lines 4-30. As such, the Applicants submit that new Claim 17 is supported by an adequate written description.

## **II. The Claims are enabled**

The Examiner further rejects Claims 4-10 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement (Office Action, pg. 4). In particular, the Examiner states "the specification does not reasonably provide enablement for a method of inhibiting Kv3.4 expression in any neuronal cell *in vivo*." The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 4 to include the element of the cell to be transfected being *in vitro* or *ex vivo*. As described above, Claim 4 has been amended to include a specific Kv3.4 target sequence. The Applicants provide experimental data for the inhibition of Kv3.4 expression in a cell *in vitro* on pages 66-67. The Applicants respectfully submit that one skilled in the art would be able to apply the methods of the Applicants to the inhibition of Kv3.4 expression in other cell types *in vitro* or *ex vivo* without undue experimentation. Methods are widely known and are described in the specification (See e.g., pages 36-44) for vectors and transfection methods for expression of nucleic acids in a variety of cell types.

The presently claimed invention is not limited to or specifically directed towards gene therapy applications. The methods of the present invention find use in research applications (e.g., drug screening, toxicology studies, etc.) that do not require delivery of a siRNA to a live subject.

Accordingly, Applicants submit that the presently claimed invention is enabled and respectfully request that the rejection be withdrawn.

**CONCLUSION**

If the Examiner believes an Interview would help expedite the allowance of this case,  
Applicants ask the Examiner to call the undersigned at 608-218-6900.

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Tanya A. Arenson  
Registration No. 47,391

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
(608) 218-6900